

Guideline

**CE Declarations of Conformity
using the safety standards
EN IEC 62368-1:2020 (3rd edition) and
IEC 62368-1:2018 (3rd edition) respectively**

March 2021

Transformer and Power Supply Division

Guideline CE Declarations of Conformity using the safety standards EN IEC 62368-1:2020 (3rd edition) and IEC 62368-1:2018 (3rd edition) respectively

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1. Introduction

The use of harmonised standards for Declarations of Conformity for CE marking has the advantage that there is a presumption of conformity and it can therefore be assumed that the safety objectives of the Low Voltage Directive (LVD) are met for such certified products. As a rule, therefore, one should use harmonised standards where possible.

Due to the current delays in listing updated harmonised standards in the Official Journal of the European Union (OJEU), manufacturers of electrical equipment find themselves in a dilemma. The version of the harmonised safety standard EN 62368-1:2014 (second edition) currently listed in the OJEU lags behind the internationally recognised state of the art.

Unfortunately, it may be some time before EN IEC 62368-1:2020 (third edition) or an equivalent is listed as a harmonised standard. The reason for the delay in the inclusion of this updated edition is not due to safety concerns about this standard, but to formal criticisms from EU member states regarding some of the detailed wording in some of the clauses which are being currently addressed by the HAS consultative process.

Manufacturers of power supplies currently have to carry out assessments according to both the current and the already obsolete editions of the 62368-1 standard in order to meet both the international and European safety requirements.

An assessment according to two different versions of the same standard prolongs the design process and creates additional work and cost.

2. Alternative Options

Instead of a complete assessment, test report and certification according to different variants of the 62368-1 standard (Option1), the intention of this guide is to show **two simpler alternative options**.

In concrete terms, the following versions of the 62368-1 safety standard are of interest:

- **IEC 62368-1:2018**
(also known as third edition), suitable for international applications (CB Reports)
- **EN 62368-1:2014 + AC:2015**
(often also called second edition), a harmonised standard suitable for European applications with corresponding presumption of conformity
- **EN IEC 62368-1:2020**
the most up-to-date EN standard, but not yet harmonised (not yet listed in the Official Journal of the EU)

From a practical point of view, the following procedures are available:

Option 1: (Current Recommendation)

Certify the power supply according to EN 62368-1:2014 + AC:2015 + A11:2017

Disadvantage: does not apply outside the EU as this version is now obsolete

Advantage: easiest way to demonstrate LVD (2014/35/EU) presumption of conformity as this version is listed in the OJEU as a harmonised standard.

Option 2: (Alternative 1)

Certify the power supply according to the non-harmonised standard IEC 62368-1:2018.

Disadvantage: not OJEU listed, so it needs a delta analysis to demonstrate LVD conformity based on the IEC 62368-1:2018 testing results and a product-specific assessment.

Advantage: most up-to-date version of the standard outside of the EU (also offered as a combined certification with UL 62368-1, 3rd. Ed.)

Option 3: (Alternative 2)

Certify the power supply according to the non-harmonised standard EN IEC 62368-1:2020.

Disadvantage: not OJEU listed, so it needs a Delta Analysis¹ to demonstrate LVD conformity based on the EN IEC 62368-1:2020 testing results and a product-specific assessment.

Advantage: can be done without using the CB scheme, which saves cost, and prepares for the possible listing of this version in OJEU in the future.

For each of these three options, you will find corresponding sample Declarations of Conformity documents listed below.

¹ The **Delta Analysis** aims at identifying and comparing the differences of the standard 62368-1 in its different variants (IEC, EN, EN IEC) and editions (Edition 2, Edition 3) - with regard to a specific product, possibly also to a specific application.

Caution! This is not the equivalent of a **risk analysis**, which stands for an in-depth analysis of the risks of the device and their consequences for health.

CENELEC Guide-32 provides guidance and assessment criteria for this.

The risk analysis must always be carried out in the course of assessing the compliance of the equipment with 2014/35/EU.

3. Sample DoCs

Below are sample Declaration of Conformity documents for power supplies issued in accordance with EMC, LVD and RoHS, in which reference is made to one of the three editions of standards mentioned above (the other standards mentioned are to be understood as examples).

As no specific language is required for the declaration of conformity in the above three directives, the manufacturer is initially free to choose it. In individual cases, market surveillance authorities can demand a translation that they understand. Many authorities accept the English language.

Option 1

Does not require further consideration as the presumption of conformity is given by the listing of the harmonised standard in the Official Journal.

EU Declaration of Conformity

<Company name> declares under our sole responsibility that the equipment named below conform to:

2014/30/EU (EMC)

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

2014/35/EU (LVD)

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

2011/65/EU (RoHS)

Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Equipment: **Product A, Product B, Product C**

Equipment description: Open type power supply

The following standards were used to assess the equipment:

EN 61000-6-1:2007

EN 61000-6-2:2005 / AC:2005

EN 61000-6-3:2007 +A1:2011 / AC:2010

EN 61000-6-4:2007 +A1:2011

[EN 62368-1:2014 + AC:2015](#)

EN IEC 63000:2018

Manufacturer: <Company name>, <Company address>

Additional information:

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Option 2

This option should be selected if a CB Scheme or a test report according to IEC 62368-1:2018 is available as a basis. The national deviations for the European member states must be observed.

EU Declaration of Conformity

<Company name> declares under our sole responsibility that the equipment named below conform to:

2014/30/EU (EMC)

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

2014/35/EU (LVD)

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

2011/65/EU (RoHS)

Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Equipment: **Product A, Product B, Product C**

Equipment description: Open type power supply

The following standards were used to assess the equipment:

EN 61000-6-1:2007

EN 61000-6-2:2005 / AC:2005

EN 61000-6-3:2007 +A1:2011 / AC:2010

EN 61000-6-4:2007 +A1:2011

[IEC 62368-1:2018 \(refer to Additional information\)](#)

EN IEC 63000:2018

Manufacturer: <Company name>, <Company address>

Additional information:

An additional delta evaluation of the above listed equipment concerning the differences between the requirements of the harmonized standard EN 62368-1:2014 (with all applicable corrections) and *IEC 62368-1:2018* has been performed and concludes that the safety objectives of the low-voltage targets (2014/35/EU) are met.

Option 3

This option is advantageous if a test report according to EN IEC 62368-1: 2020 is available as a basis and the cost of applying for a CB Scheme report is not economical:

EU Declaration of Conformity

<Company name> declares under our sole responsibility that the equipment named below conform to:

2014/30/EU (EMC)

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

2014/35/EU (LVD)

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

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EN 61000-6-3:2007 +A1:2011 / AC:2010

EN 61000-6-4:2007 +A1:2011

[EN IEC 62368-1:2020 + AC:2020 \(refer to Additional information\)](#)

EN IEC 63000:2018

Manufacturer: <Company name>, <Company address>

Additional information:

An additional delta evaluation of the above listed equipment concerning the differences between the requirements of the harmonized standard EN 62368-1:2014 (with all applicable corrections) and *EN IEC 62368-1:2020* has been performed and concludes that the safety objectives of the low-voltage targets (2014/35/EU) are met.



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